Rules - 2004

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DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-258S]
Dispensing of Controlled Substances for the Treatment of Pain
AGENCY: Drug Enforcement Administration (DEA), Department of Justice.
ACTION: Interim policy statement.

SUMMARY: In August 2004, DEA published on its Office of Diversion Control Web site a document entitled: "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel" (August 2004 FAQ). The August 2004 FAQ was not published in the Federal Register and was not an official statement of the agency. DEA subsequently withdrew the document because it contained misstatements. This interim policy statement explains how some of the statements in the August 2004 FAQ were erroneous. In addition, this interim statement explains how DEA plans to address in a future Federal Register document the issue of dispensing controlled substances for the treatment of pain.
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SUPPLEMENTARY INFORMATION: In August 2004, DEA published on its Office of Diversion Control Web site a document entitled: "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel" (August 2004 FAQ). For the reasons provided below, the August 2004 FAQ was not an official statement of the agency and DEA subsequently withdrew the document because it contained misstatements. Nonetheless, the subject matter--dispensing controlled substances for the treatment of pain--is extremely important to the public health and welfare. As the agency primarily responsible for enforcement and administration of the federal laws and regulations governing controlled substances, DEA believes that further discussion of the subject is warranted for two fundamental reasons. First, the abuse of pharmaceutical narcotics and other prescription controlled substances is increasing in the United States. According to the latest National Survey on Drug Use and Health, which is published by the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), the number of Americans aged 12 or older who have engaged in illicit (nonmedical) use of pain relievers during their lifetime has risen to more than 31 million.\1\ A portion of this type of drug abuse is directly facilitated by a small number of physicians who dispense controlled substances for other than legitimate medical purposes and then fraudulently claim that the drugs were dispensed for the treatment of pain.

\1\ The report is available on the SAMHSA Web site at http://oas.samhsa.gov/NHSDA/2k3NSDUH/2k3results.htm.

Second, chronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified. DEA recognizes that the overwhelming majority of physicians dispense controlled substances lawfully for legitimate medical reasons, including the treatment of pain. Accordingly, DEA

plans to address the subject of dispensing controlled substances for the treatment of pain in a future Federal Register document, taking into consideration the views of the medical community. The document will be aimed at providing guidance and reassurance to physicians who engage in
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legitimate pain treatment while deterring the unlawful conduct of a small number of physicians and other DEA registrants who exploit the term "pain treatment" as a pretext to engage in prescription drug trafficking. In the meantime, the agency wishes to correct here a few of the significant misstatements contained in the August 2004 FAQ.

Misstatements in the August 2004 FAQ

Although not an exhaustive discussion, the following is an explanation of some of the misstatements that were contained in the August 2004 FAQ.

Commencement of investigations--The August 2004 FAQ erroneously stated: "The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves, indicate a problem, and they should not be used as the sole basis for an investigation by regulators or law enforcement." In fact, each of the foregoing factors--though not necessarily determinative--may indeed be indicative of diversion. As one federal appeals court has correctly stated, one can glean from the reported cases in which physicians have been convicted of dispensing controlled substances for other than a legitimate medical purpose "certain recurring concomitance of condemned behavior," such as the following:

> (1) An inordinately large quantity of controlled substances was prescribed.
> (2) Large numbers of prescriptions were issued.
> (3) No physical examination was given.
> (4) The physician warned the patient to fill prescriptions at different drug stores.
> (5) The physician issued prescriptions to a patient known to be delivering the drugs to others.
> (6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
> (7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
> (8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
> (9) The physician wrote more than one prescription on occasions in order to spread them out.

United States v. Rosen, 582 F.2d 1032, 1035-1036 (5th Cir. 1978) (citations omitted).

Moreover, it is a longstanding legal principle that the Government "can investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not." United States v. Morton Salt Co., 338 U.S. 632, 642-643 (1950). It would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the Controlled Substances Act (CSA).

Refills of schedule II prescriptions--The August 2004 FAQ stated: "Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates." (Italics added.) The first part of this sentence is correct, as the CSA expressly states: "No prescription for a controlled substance in schedule II may be refilled." 21 U.S.C. 829(a). However, the second part of the sentence (italicized above) is incorrect. For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance. To do so conflicts with one of the fundamental purposes of
section 829(a). Indeed, as the factors quoted above from the Rosen case indicate, writing multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes. It is worth noting here that the DEA regulations setting forth the requirements for the issuance of a controlled substance prescription are set forth in 21 CFR 1306.01-1306.27.

Reselling of controlled substances--The August 2004 FAQ listed a number of behaviors, or "red flags," that are "probable indicators of abuse, addiction, or diversion." These behaviors include "selling medications." The document suggested that certain steps be taken to deal with such indicators, including "appropriate management" and possible referral to an addiction specialist. The document went on to state that these behaviors (including reselling medications) "should not be taken to mean that a patient does not have pain, or that opioid therapy is contraindicated." The document also stated: "Management may or may not include continuation of therapy, depending on the circumstances." Finally, the document stated that "if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is recommended." (Italics added.)

The behaviors listed in the August 2004 FAQ as "red flags" are indeed indicators of possible diversion. However, the August 2004 FAQ understated the degree of caution that a physician must exercise to minimize the likelihood of diversion when dispensing controlled substances to known or suspected addicts. If a physician is aware that a patient is a drug addict and/or has resold prescription narcotics, it is not merely "recommended" that the physician engage in additional monitoring of the patient's use of narcotics. Rather, as a DEA registrant, the physician has a responsibility to exercise a much greater degree of oversight to prevent diversion in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. Under no circumstances may a physician dispense controlled substances with the knowledge that they will be used for a nonmedical purpose or that they will be resold by the patient.

In a similar vein, the August 2004 FAQ incorrectly minimized the potential significance of a family member or friend expressing concern to the physician that the patient may be abusing the pain medication. The document stated:

Family and friends, or health care providers who are not directly involved in the therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded fear of addiction; they may be exacerbated by widespread, sometimes inaccurate media coverage about abuse of opioid pain medications.

While it is true that concerns of family members are not always determinative of whether the patient is engaged in drug abuse, the above-quoted statement is incorrect to the extent it implies that physicians may simply disregard such concerns expressed to them by family members or friends. Indeed, a family member or friend might be aware of information that the physician does not possess regarding a patient's drug abuse. Given the addictive and sometimes deadly nature of prescription narcotic abuse, the tremendous volume of such drug

abuse in the United States, and the propensity of many drug addicts to attempt to deceive physicians in order to obtain controlled substances for the purpose of abuse, a physician should seriously consider any sincerely expressed concerns about drug abuse conveyed by family members and friends.

It bears emphasis that none of the principles summarized above is new. Rather, these are concepts that have been incorporated for more than 80

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years into the federal laws and regulations governing drugs of abuse and are reflected in published federal court decisions and DEA final administrative orders. A more detailed recitation of these principles, as they relate to the dispensing of controlled substances for the treatment of pain, will be provided in a future Federal Register document to be published by the agency.

Nature of This Document and the August 2004 FAQ Under the Administrative Procedure Act

This document is a statement of policy within the meaning of the Administrative Procedure Act (APA). It is termed an "interim" statement to indicate that a more complete statement on the subject will subsequently be issued by the agency. (Given the misstatements in the August 2004 FAQ, and the significant questions DEA has received following the withdrawal of that document, an immediate preliminary explanation is warranted.) The APA expressly requires agencies to make available to the public and publish in the Federal Register statements of general policy and interpretations formulated and adopted by the agency. 5 U.S.C. 552(a)(1)(D). Further, the APA contemplates that agencies shall issue policy statements without engaging in the notice-and-comment proceedings that are required for legislative rules. 5 U.S.C. 553(b)(A). This is because policy statements, unlike legislative rules, are not binding. Consistent with these APA principles, this document does not create any new substantive requirements or change the rights and duties of any member of the public; nor is DEA applying the CSA or DEA regulations in a new manner as a result of this document. Rather, this document provides the public with

DEA's policy for ensuring that the law administered by the agency relating to the subject matter of this document is faithfully executed.

It also bears emphasis that the August 2004 FAQ was not an official statement of the agency. As indicated above, the APA requires publication in the Federal Register of agency policy statements or interpretations of the law administered by the agency. The August 2004 FAQ was not published by the agency in the Federal Register and did not constitute an authoritative or official statement of the agency.

Dated: November 12, 2004.

Michele M. Leonhart,

Deputy Administrator.

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